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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,730	06/16/2000	Dion Charles Chewe Martin	3869-006	2822

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GOTTLIEB RACKMAN & REISMAN PC
270 MADISON AVENUE
8TH FLOOR
NEW YORK, NY 100160601

EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 05/03/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,730	MARTIN ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/29/2004 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31-34 and 39* is/are allowed.

6)☒ Claim(s) *1-4,6-15,25-30 and 35-38* is/are rejected.

7)☒ Claim(s) *5 and 16-24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4,6-15,25-30,35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Gruenke et al. ('995).

As to claim 1, Gruenke et al. (see abstract line 3) disclose a respiratory apparatus for delivering a flow of air to a patient suffering from sleep disorder breathing comprising: a blower (18) that generates a flow of pressurized air; a patient interface (14) adapted to deliver air from said blower to the patient; a control unit (20) coupled to said patient interface (38) and adapted to sense a parameter (i.e. pressure) characteristic of said flow of air, said control unit including a[n] display adjusting circuit means (87 and col.12, lines 45-61) for operating on said parameter to generate a signal indicative of the breathing pattern of the patient; said control unit further including a first averager (col.12, lines 45-61) used to determine a first average of said signal, said display adjusting circuit means for restricting said signal within a predetermined display range in response to said first average in a manner that does not change the pressure of the air delivered from the blower to the patient; and a display (88) adapted to show said signal. As to the functional language "...in a manner that does not change the pressure of the air delivered from the blower to the patient...", it is submitted that the pressure of the air

delivered to a patient does not change unless the sensed parameter (pressure) is outside the maximum allowed error as disclosed at col.12, lines 60 and 64.

As to claim 2, Gruenke et al. disclose said control unit (20) having a pressure sensor (38) adapted to detect a pressure signal indicative of a pressure within said patient interface, said parameter comprising said pressure signal.

As to claim 3, Gruenke et al. disclose said control unit (20) having a baseline generator generating a baseline signal, said signal being related to said parameter and said baseline signal.

As to claim 4, Gruenke et al. disclose the baseline generator being coupled to said first averager and has coded control instructions to set the baseline signal to a value related to said first average.

As to claim 6, Gruenke et al. disclose a respiratory apparatus used to provide air under controlled conditions to a patient with a pulmonary deficiency, said respiratory apparatus comprising: a blower (18) that generates a flow of pressurized air; a patient interface (14) that delivers said flow of air to the patient; a control unit (20) coupled to one of said blower and patient interface to derive a parameter indicative of said flow of air and the breathing of the patient, said control unit having a signal processing unit that processes said parameter to generate a respiration signal indicative of said breathing and a display adjusting circuit means (87 and col.12, lines 45-61) for determining an average value of said respiration signal and for adjusting said respiration signal based on said average value to restrict said respiration signal to a predetermined display range in a manner that does not change the air treatment delivered from the blower to

the patient; and a display (88) adapted to show said respiration signal. As to the functional language "...in a manner that does not change the pressure of the air delivered from the blower to the patient...", it is submitted that the pressure of the air delivered to a patient does not change unless the sensed parameter (pressure) is outside the maximum allowed error as disclosed at col.12, lines 60 and 64.

As to claim 7, the display adjusting circuit means of Gruenke et al. includes a programmable microprocessor which is "adapted" to be programmed with instructions to perform a variety of functions including determining a short term average value and a long term average value and to adjust the respiration signal in a first and second manner in dependence upon the respective short term average and long term average values. Consequently, the display circuit adjusting means is fully capable of performing the recited functions of determining a short term average value and a long term average value and to adjust the respiration signal in a first and second manner in dependence upon the respective short term average and long term average values due to its adaptability to be programmed. Claim 7 does not recite any structural elements which physically distinguish the display adjusting circuit means of Gruenke et al..

Each of claims 8-13 recites the display adjusting circuit means being adapted to generate a signal and/or process the generated signal in a desired manner. As indicated above with respect to claim 7, the display adjusting circuit means of Gruenke et al. includes a programmable microprocessor which is "adapted" to be programmed with instructions to perform a variety of functions including the generation of various electrical signals as well as processing the generated signals in a variety of ways.

Consequently, the display circuit adjusting means is fully capable of performing the functions recited in each of claims 8-13 due to its adaptability to be programmed. None of claims 8-13 recite any structural elements which physically distinguish the display adjusting circuit means of Gruenke et al..

As to claim 14, Gruenke et al. disclose a method for presenting a respiration signal indicative of the patient's breathing pattern in a respiratory apparatus adapted to provide a flow of pressurized air to a patient the method comprising: determining a parameter (via pressure sensor 38) within the device related to the flow of pressurized air and the breathing of the patient; adjusting said parameter based on a baseline signal (i.e. set point pressure as disclosed at col.6, lines 55-60) to generate a respiration signal within a predetermined display range based on an average value of said respiration signal in a manner that does not change the respiratory treatment delivered to the patient; and displaying (88) said respiration signal. As to the functional language "...in a manner that does not change the pressure of the air delivered from the blower to the patient...", it is submitted that the pressure of the air delivered to a patient does not change unless the sensed parameter (pressure) is outside the maximum allowed error as disclosed at col.12, lines 60 and 64.

As to claim 15, Gruenke et al. disclose taking a difference between said baseline signal (i.e. set point pressure at col.6, lines 55-60) and said parameter (via pressure sensor 38) to derive an adjusted signal (i.e. a signal indicative of inhalation pressure or exhalation pressure). That is, the adjusted signal is the baseline signal plus another

signal during inhalation and the baseline signal plus or minus another signal during exhalation.

As to claim 25, the parameter in Gruenke et al. is the pressure at which air is provided to the patient as determined by pressure sensor #38.

As to claim 26, Gruenke et al. disclose a method of keeping a respiratory signal from a patient within a predetermined dynamic range (i.e. maximum allowed error as disclosed as col.12, lines 60 and 64) of an output/display unit comprising the steps of: determining a parameter (via pressure sensor 38) indicative of the patient's respiration; and automatically adjusting (col.6, lines 55-60) a presentation of said parameter based on a baseline signal (i.e. set point pressure as disclosed at col.6, lines 55-60) to generate the respiration signal within said predetermined dynamic range of an output display unit in a manner that does not change the pressure of the air delivered from the blower (18) to the patient. As to the functional language "...in a manner that does not change the pressure of the air delivered from the blower to the patient...", it is submitted that the pressure of the air delivered to a patient does not change unless the sensed parameter (pressure) is outside the maximum allowed error as disclosed at col.12, lines 60 and 64.

As to claim 27, Gruenke et al. automatically adjusts the parameter (col.6, lines 55-60 and col.12, lines 39-61) when the parameter (i.e. mask pressure as measured via sensor 38) is outside said predetermined range (i.e. maximum allowed error as disclosed as col.12, lines 60 and 64) for a predetermined duration (i.e. the amount of

time between the sensing of the parameter and the determination of whether it outside the maximum allow error range).

As to claims 28-30, Gruenke et al. the predetermined duration is the time between consecutive inhalations or exhalations (which is "approximately" 6 sec.) which is long compared to an individual inhalation or exhalation.

As to claims 35 and 36, the control unit (20) in Gruenke et al. is configured and adapted to control changes in the pressure of pressurized air (col.6, lines 30-34).

As to claims 37 and 38, the control unit (20) of Gruenke et al. performs the step of controlling changes in the pressure of the pressurized air for treatment of the patient (col.6, lines 30-34).

Claim Objections

3. Claim 1 is objected to because of the following informalities: in line 6, "...an display..." should read –a display--. Appropriate correction is required.

Allowable Subject Matter

4. Claims 5,16-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 31-34,39 are allowed.

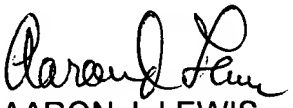
Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant respiratory devices for delivering a flow of air to a patient suffering from a sleep disorder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
April 30, 2004